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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,745	12/21/2001	James A. Brady	9386.17711-C	4890

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EXAMINER	
BIANCO, PATRICIA	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,745	BRADY ET AL.	
	Examiner	Art Unit	
	Patricia M Bianco	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8,9,26-49,59 and 60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8,9,26-49,59 and 60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 December 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/12; 38/; 2/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

An amendment was filed February 13th, 2004. Claims 8, 26, 32, 38 & 44 were amended. Claims 1-7, 10-25 & 50-58 were cancelled. Claims 59 & 60 were added.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "*primary treatment means*," "*a primary treatment modality*," and "*auxiliary treatment means*" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

Applicant has indicated co-pending applications in the first paragraph of the specification. The first page of the specification should be updated to clarify the status of all related applications noted in the first paragraph of the specification. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent

application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: amended claims 26 & 32 now claim "*primary treatment means*," "*a primary treatment modality*," and "*auxiliary treatment means*" in the claims; amended claim 38 now claims "*a primary treatment modality*."

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 26, 32 & 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The amended claims 26 & 32 now claim "*primary treatment means*," "*a primary treatment modality*," and "*auxiliary treatment means*" in the claims; amended claim 38 now claims "*a primary treatment modality*." It is unclear based on the specification as originally filed what these limitations are intended to claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26-39 and 44-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Strahilevitz (6,039,946). Strahilevitz discloses an extracorporeal affinity adsorption device that is used for the treatment of a mammalian fluid, such as blood or plasma, in an on-line, extracorporeal treatment system. The adsorption device uses Chelex, a polymeric resin, for removing immunoadsorbants from the blood or plasma. As shown in figures 4 & 5, a first blood treatment device, which is, as best can be understood by the examiner, equivalent to applicant's "primary treatment modality." The blood is first treated in the first device and then the treated blood is passed through the adsorbent column, which is, as best can be understood by the examiner, equivalent to applicant's "auxiliary treatment means" to remove pro- or anti-inflammatory stimulators from the treated blood. With respect to the claimed limitations of claims 27-31, the fluids are not given patentable weight since they were not positively recited in claim 26 and are a product of the intended use of the device. With respect to claims 34-37 & 46-49, the recitation that the polymeric material is "prepared by" a process has not been given patentable weight since it is a product-by-process limitation. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the

same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8, 9, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strahilevitz ('946). Strahilevitz discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the adsorption medium is characterized by a Biocompatibility Index of not greater than 14,

or not greater than 7. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polymeric material of the adsorbant to be characterized by a Biocompatibility Index of not greater than 14, or not greater than 7, since it has been held in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin,* 125 USPQ 416.

Claims 40-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strahilevitz ('946) in vie of Hirai et al. ('362). Strahilevitz discloses the invention substantially as claimed, however, fails to disclose specifically that the physiologic fluid is lymphatic fluid, synovial fluid, cerebrospinal fluid, or spinal fluid.

Hirai et al. (hereafter Hirai) discloses an adsorbant system having an inlet and outlet for fluid (1/2), and an adsorbant means (3) within a column 6 and a vessel 7 or housing. The adsorbant means is a styrene-divinylbenzene copolymer. The system is used for removing interleukins (i.e. cytokines) from a body fluid. The body fluid may be ascites, lymph, or synovial fluids.

At the time of the invention, it would have been obvious to modify the method for using the apparatus of Strahilevitz as taught by Hirai, to treat fluid such as be ascites, lymph, synovial, spinal or cerebrospinal (CSF) fluids. Ascites is an accumulation of fluid in the peritoneal cavity; therefore in the broadest interpretation of the claims, this includes peritoneal dialysis solution since it inherently accumulates in the peritoneal cavity to perform its dialyzing function. With respect to the fluid being CSF or spinal

fluid, it would have been obvious to choose either, based on the treatment required for a specific patient, since interleukins are widely present in both fluids during infection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M Bianco whose telephone number is (703) 305-1482. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 30th, 2004

Patricia M Bianco
Primary Examiner
Art Unit 3762